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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,334	12/05/2000	Bradley S. Butler	P00424	8126

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EXAMINER

WINGOOD, PAMELA LYNN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/730,334

Applicant(s)

Butler et al.

Examiner

Pamela Wingood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 9, 12, 15, 16, and 20-22 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 10, 11, 13, 14, and 17-19 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Oath/Declaration*

1. The Oath is objected to for the following reason:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

### *Specification*

2. The disclosure is objected to because of the following informalities: Throughout the Specification, the word "stylette" appears. According to *Webster's Ninth New Collegiate Dictionary*, the proper spelling of the word is "stylet".

On Page 26, in the second to the last line of the first full paragraph, delete "thoseskilled" and insert --those skilled--.

Appropriate correction is required.

### *Claim Objections*

3. Claims 5, 20 and 21 are objected to because of the following informalities: In the above identified Claims, the word "stylette" appears. According to *Webster's Ninth New Collegiate Dictionary*, the proper spelling of the word is "stylet". Regarding claims 5 and 12, the Markush

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structure should read “an element selected from the group. . . “. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 12 at Subparagraph c), the phrase “consisting of” should be followed by “:” and each element except for the last one should be followed by “;”.

The first three lines of the preamble of Claim 20 indicate the claim will be an apparatus claim; however, the last phrase of the claim and Steps of the claim are actually claiming steps in a method. The claim is actually a method claim and accordingly, the first line of the claim should read “The spinal fluid collection method . . . “. Similarly, the preamble of Claim 21 should be changed to reflect the method.

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***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 4, 5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerber et al.

Gerber et al. discloses a spinal fluid collection system disclosing a plurality of CSF tubes (Col. 2, lns. 59-65) to receive, seal (with element 82) and transport (Col. 5, lns. 53-55) cerebrospinal fluid, a spinal tap assembly (10), a holder (50, 80) to hold the CSF tubes and a surface in between elements (50) and (80) in Figure 1, to allow for single handed manipulation with either hand. The holder, of a transparent material (Fig. 1) also stably holds the needle (11) and the stylet (14), the sleeve at (12) in Fig. (2c) holding the needle and stylet.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 2, 3 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber et al in view of Berry.

Gerber et al. discloses the limitations above but does not disclose the use of an internally sterile package to seal the holder and the CSF tubes.

Berry discloses a kit having a holder and medical sharps in a sealed sterile environment in an analogous art for the purpose of ensuring the patients safety. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the device of Gerber et al. as shown by Berry because the use of a sterile containment device would ensure that contaminants are not introduced to the patient during the sterile technique (Col. 2, lns. 29-31)

Regarding Claim 3, the subject matter is disclosed within the Gerber et al reference at element (10).

10. Claims 8, 9, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber et al. in view of Tyler.

Gerber et al. discloses the limitations above as well as the use of transparent holder assembly (Fig. 1) but does not disclose the material of the holder.

Tyler discloses the use of a transparent plastic material in the analogous fluid collection art for the purpose of providing adequate structural strength. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Gerber et al. in view of Tyler because the use of a plastic material would prevent the material from breakage in comparison to other materials and still provide transparency.

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*Allowable Subject Matter*

11. Claims 20 and 21 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action. The following is a statement of reasons for the indication of allowable subject matter: Prior art of record did not suggest or disclose a spinal fluid collection system or method for removing said stylet from the spinal needle and placing the stylet in the needle holder.

12. Claims 6, 7, 10, 11, 13, 14, 17, 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Prior art of record did not suggest or disclose a spinal fluid collection system having a holder structured and arranged to hold, when the holder is in an upright position, at a second portion of the holder any element selected from the group.

*Conclusion*

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

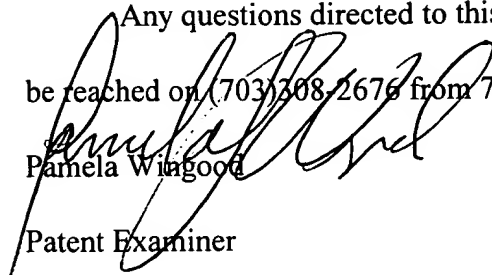
A. Lazarus et al. (4,128,173) discloses a fluid treatment apparatus having a plurality of sterile openable and sealed packages for storing and transporting various medical devices.

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Any questions directed to this application should be directed to Pamela Wingood who can be reached on (703) 308-2676 from 7:30-5:00PM on Monday-Thursday and every other Friday.



Pamela Wingood

Patent Examiner

January 27, 2001